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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,697	01/03/2001	Charles W. Bishop	17620/9316	1609

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EXAMINER

CHONG, YONG SOO

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/753,697	Applicant(s) BISHOP ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,11 and 13-104 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,18-28,31,33,36,37,50 and 65-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-3, 11, 13-14, 17, 29-30, 32, 34-35, 38-49, 51-64, 68-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-3 (in part), 11 (in part), 13-14 (in part), 17, 29-30, 32, 34, 35 (in part), 38, 43-45, 51-53, 58-61, 68-69, 78-79, 85-90, 91 (in part), 92, 100-104 (in part) are drawn to a method of maintaining bone mass, treating bone loss or bone mineral content, classified in 514/168.
- II. Claims 2-3 (in part), 11 (in part), 13-14 (in part), 17, 29-30, 32, 34, 39, 43-44, 46, 51, 54, 58-59, 62, 68, 70, 80, 85-90, 91 (in part), 93, 100-104 (in part) are drawn to a method of treating hyperparathyroidism, classified in 514/168.
- III. Claims 2-3 (in part), 11 (in part), 13-14 (in part), 17, 29-30, 32, 34, 35 (in part), 40, 43-44, 47, 51, 55-56, 58-59, 63-64, 68, 71-76, 81-83, 85-90, 91 (in part), 94-99, 100-104 (in part) are drawn to a method of inhibiting hyperproliferation, inducing or enhancing cell differentiation, classified in 514/168.
- IV. Claims 2-3 (in part), 11 (in part), 13-14 (in part), 17, 29-30, 32, 34, 41, 43-44, 48, 51, 58-59, 68, 85-90, 91 (in part), 100-104 (in part) are drawn to a method of modulating immune response, classified in 514/168.
- V. Claims 2-3 (in part), 11 (in part), 13-14 (in part), 17, 29-30, 32, 34, 42-44, 49, 51, 57-59, 68, 77, 84-90, 91 (in part), 100-104 (in part) are drawn to a method of modulating inflammatory response, classified in 514/168.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating bone disorders and a method of treating hyperparathyroidism. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention II, restriction for examination purposes as indicated is proper.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating bone disorders and a method of treating hyperproliferation. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention III, restriction for examination purposes as indicated is proper.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions are drawn to a method of treating bone disorders and a method of modulating immune response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention IV, restriction for examination purposes as indicated is proper.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating bone disorders and a method of modulating inflammatory response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention V, restriction for examination purposes as indicated is proper.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating hyperparathyroidism and a method of treating hyperproliferation. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are

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distinct for the reasons given above and the search required for Invention II is not required for Invention III, restriction for examination purposes as indicated is proper.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating hyperparathyroidism and a method of modulating immune response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention II is not required for Invention IV, restriction for examination purposes as indicated is proper.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating hyperparathyroidism and a method of modulating inflammatory response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention II is not required for Invention V, restriction for examination purposes as indicated is proper.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating hyperproliferation and a method of modulating immune response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention III is not required for Invention IV, restriction for examination purposes as indicated is proper.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treating hyperproliferation and a method of modulating inflammatory response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention III is not required for Invention V, restriction for examination purposes as indicated is proper.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of modulating immune

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response and a method of modulating inflammatory response. Both disorders have different etiologies, different morphologies, and different modes of treatment. The search for one will not lead to the search of the other. Because these inventions are distinct for the reasons given above and the search required for Invention IV is not required for Invention V, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

If Invention III is elected:

This application contains claims directed to the following patentably distinct species of the claimed Invention III, which is drawn to a method of treating hyperproliferation with 24-hydroxy Vitamin D compounds. Claims 40, 47, 55-56, 63-64, 81-83 are generic to a plurality of disclosed patentably distinct species. Claims 71-76, 94-99 lists the following patentably distinct forms of hyperproliferation: psoriasis, skin cancer, breast cancer, colon cancer, prostate cancer, and prostatic hyperplasia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Note the court in *In re Herrick et al.* and *In re Joyce et al.* (both at 115 USPQ 412) held that an election of species requirement was, in fact, a restriction requirement.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP

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§ 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

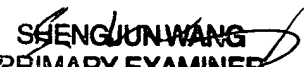
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC


SHENGJUN WANG
PRIMARY EXAMINER